K070437

MAY - 9 2007

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of PRO-DENSE™ Bone Void Filler.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 29, 2007
Contact Person:	Ryan M. Belaney Regulatory Affairs Specialist I
Proprietary Name:	**PRO-DENSE™** Bone Graft Substitute
Common Name:	Bone Graft Substitute
Classification Name and Reference:	21 CFR 888.3045 – Resorbable Calcium Salt Bone Void Filler Device – Class II
Device Product Code and Panel Code:	Orthopedic/87/MQV

DEVICE INFORMATION

A. INTENDED USE

PRO-DENSE™ resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis) to cure in-situ. These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE™ paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

B. DEVICE DESCRIPTION

The PRO-DENSE™ Bone Graft Substitute material is indicated as a bone graft substitute to be injected, digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system to cure in-situ. A brief description of the PRO-DENSE™ implant and a summary of additional performance/marketing claims are provided below.

IMPLANT DESCRIPTION

PRO-DENSE™ consists of a calcium sulfate – calcium phosphate composite bone graft substitute consisting of a powder component and an aqueous mixing solution. When the two components are mixed, according to directions, an injectable paste is formed which subsequently hardens via hydration reactions. The paste can be injected and cured *in situ* or gently packed into bony defects.

NON-CLINICAL PERFORMANCE/MARKETING CLAIMS

*All claims are based on a critically sized canine proximal humerus defect model. It is unknown how results from the canine model compare with clinical results in humans.

- **Claim 1:** The newly regenerated bone in the PRO-DENSE™ injectable treated defects exhibited a 645% average increase in compressive strength at 13 weeks versus defects treated with autograft: Stronger than autograft.*

  Substantiation: Ultimate compressive strength in PRO-DENSE™ injectable increased 645% compared to the autograft group.

- **Claim 2:** Histomorphometry reveals that the amount of newly regenerated bone of the PRO-DENSE™ injectable treated defects at 13 weeks demonstrated a statistically significant 170% average increase in new bone formation versus defects treated with autograft. PRO-DENSE™ injectable new bone area fraction is on average 170% denser than autograft at 13 weeks: Denser than autograft.*

  Substantiation: Results showed that PRO-DENSE™ injectable demonstrated a 170% average increase in new bone volume over autograft treatment.

- **Claim 3**: The accelerated rate of healing of the PRO-DENSE treated defects compared to those treated with autograft is principally evident by the higher density bone (i.e., 170% average increase in area fraction of new bone compared to autograft at 13 weeks) and superior average mechanical properties at 13 weeks: Faster than autograft.*

  Substantiation: Results showed that PRO-DENSE™ injectable demonstrated a, statistically significant, 170% average increase in new bone volume over autograft treatment. Ultimate compressive strength and elastic modulus in PRO-DENSE™ injectable increased 645% and 600% respectively, compared to the autograft group.

- **Claim 4:** Newly regenerated bone from the PRO-DENSE™ injectable treated defects remodeled to normal host bone, demonstrated by normal trabecular architecture histologically, and no significant difference in mechanical properties (compressive strength and modulus of elasticity) at the 26 week timepoint: Remodels to normal bone.*

  Substantiation: Area fraction of new bone results of PRO-DENSE™ injectable showed no statistically significant difference to normal bone area fraction, indicating that the PRO-DENSE™ injectable has substantially remodeled toward the normal state of trabecular bone by 26 weeks. Additionally, ultimate compressive strength and modulus of elasticity of PRO-DENSE™ injectable at 26 weeks showed no statistically significant difference to normal bone samples.

- **Claim 5:** The compressive modulus of the newly regenerated bone from the PRO-DENSE™ injectable treated defects at both 13 and 26 weeks falls within the published range for normal human cancellous bone: No modulus mismatch.*

  Substantiation: An examination of published values of compressive modulus for human cancellous bone shows that even the highest value measured for PRO-DENSE™ injectable treated defects is still well within the range of normal cancellous bone.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the PRO-DENSE™ Bone Graft Substitute are substantially equivalent to the previously cleared MIIG® SR Bone Void Filler 510(k): K060011. Additionally, the safety and effectiveness of the PRO-DENSE™ Bone Graft Substitute is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Mr. Ryan M. Belaney
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

MAY - 9 2007

Re: K070437
Trade/Device Name: PRO-DENSE™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: April 6, 2007
Received: April 9, 2007

Dear Mr. Belaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K070437

Device Name: PRO-DENSE™

Indications For Use:

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PRO-DENSE™ is provided sterile for single use only.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use __√__
(Per21 CFR 801.109)

510(k) Number K070437 OR

K070437

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

Over-The Counter Use ____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)